UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF OHIO

GENE GEARY, RICKY LANE, SUSAN LANE, TERESA LAWRENCE, TRACEY LAYNE, DAWN MILLER, CLARENCE MULLINS, PAULINE PARKS, CHESTER SMITH, LINDA SUE SMITH, LISA SNYDER-BLEVINS, KELLY WILLIAMS, BEVERLY WILLIAMS, CINDY WALLACE, WILLIAM KIGHT, MARY KIGHT, GLENN WELCH and DAWN WELCH, **Plaintiffs,** **v.** **LIBERTY INDUSTRIES, INC., and UNIFIRST CORPORATION D/B/A UNICLEAN CLEANROOM SERVICES,** **Defendants.**	**Case No. 14-764** **COMPLAINT** **DEMAND FOR JURY TRIAL**

Plaintiffs GENE GEARY, RICKY LANE, SUSAN LANE, TRACEY LAYNE, TERESA LAWRENCE, DAWN MILLER, CLARENCE MULLINS, PAULINE PARKS, CHESTER SMITH, LINDA SUE SMITH, LISA SNYDER-BLEVINS, KELLY WILLIAMS, BEVERLY WILLIAMS, CINDY WALLACE, WILLIAM KIGHT, MARY KIGHT, GLENN WELCH and DAWN WELCH, sue Defendants and allege:

INTRODUCTION

1. This lawsuit arises from an outbreak of fungal meningitis and other infections that has affected individuals in Ohio as well as another nineteen other states. To date, more than over seven hundred people have been diagnosed with meningitis, fungal infections and/or abscesses, and other injuries.

2. The United States Food and Drug Administration ("FDA") and the Centers for Disease Control and Prevention ("CDC") have confirmed the presence of fungus in unopened vials of NECC's methylprednisolone acetate ("MPA"). The FDA and CDC have also identified bacteria and/or fungus present in NECC-supplied preservative-free injectable betamethasone, preservative-free triamcinolone, and cardioplegia solution. Some of the contaminants identified in these products are known to cause human disease. All products made by NECC have been recalled.

3. No one disputes that the contaminated products that caused these horrific injuries were made by New England Compounding Company, Inc. ("NECC"). No one seriously disputes that the deplorable conditions at NECC contributed to this outbreak. But the story does not begin or end with NECC: Multiple actors contributed to the chain of events that lead to these 64 deaths.

4. Defendant Liberty Industries, Inc. ("Liberty") designed, manufactured, and installed the cleanrooms used to compound, mix, prepare, and assemble the contaminated products. Liberty's cleanrooms contained defects that made them unsuitable for their intended use and vulnerable to the manufacture of contaminated products. Without Liberty, there would have been no clean rooms for NECC to compound medicines in and without the defects in Liberty's clean rooms, the contamination may well have been avoided. This Defendant is subject to long arm jurisdiction, and may be properly brought before this Court.

5. Defendant UniFirst Corporation ("UniFirst") was hired by NECC to clean the NECC and Ameridose clean rooms, including the clean rooms where the contaminated products were manufactured. UniFirst advertises that its services will "improve the safety and cleanliness" of a business facility. UniFirst contracted with NECC to, and did, provide cleaning services to NECC and/or Ameridose, including with respect to the clean rooms. NECC's internal records report numerous instances of reported mold and bacterial contamination in the months leading up to the outbreak. UniFirst failed to provide adequate cleaning services that would have prevented contamination of the drugs made in those clean rooms. UniFirst is a foreign corporation with a registered agent, Prentice Hall Corporation System, Inc., located at 50 West Broad Street Suite 1800, Columbus Ohio.

6. Not one person would have developed a fungal infection if hospitals, clinics, healthcare facilities, and/or physicians had not given these contaminated medications to patients. Hospitals, clinics, healthcare facilities and/or physicians in at least 20 states, including Ohio, injected patients with contaminated drugs from NECC. These clinics ordered these medications (often with fake patient names), purchased the contaminated medications, received the contaminated medications, stored the contaminated medications, and injected the contaminated

medications into patients – often dozens of patients. Clinics often disregarded the prevailing industry guidelines and Massachusetts pharmacy regulations requiring individual medications to be compounded in response to receiving a prescription for a particular patient. Clinics did so out of convenience and greed: ordering large doses of steroids and products in bulk allowed them to stock their shelves without going through the "hassle" (but really safeguard) of identifying particular patients who would receive the drug. NECC's price for MPA and other products was, generally, lower than the prices for brand name methylprednisolone acetate (depomedrol) manufactured by Pfizer.

7. Plaintiffs seek compensatory and exemplary damages, and all other available remedies as a result of injuries caused by NECC's defective products and/or services. Plaintiffs make the following allegations based upon their personal knowledge and upon information and belief, as well as upon their attorneys' investigative efforts.

I. JURISDICTION AND VENUE

8. This Court has original, diversity jurisdiction over the claims of Plaintiffs pursuant to 28 U.S.C. §1332 (a), as the Plaintiffs and Defendants are citizens of different States and the amount in controversy is greater than $75,000.00 for each Plaintiff.

9. This Court has subject matter jurisdiction over the parties pursuant to 28 U.S.C. § 1334(b) because, as described herein, each claim asserted is related to a case under title 11, because the outcome of the proceeding could have some effect on the bankruptcy estate.

10. On December 21, 2012, NECC filed a petition for Bankruptcy protection under Chapter 11 of the Bankruptcy Code: In re: New England Compounding Pharmacy, Inc., Debtor, United States Bankruptcy Court for the District of Massachusetts Case no. 12:19882 HJB. A United States Trustee was subsequently appointed to administer the Bankruptcy Estate.

II. PARTIES

Plaintiffs

11. The listed Plaintiffs are individuals who suffered injury or distress as a direct and proximate result of being administered one or more NECC Contaminated Drugs compounded, sold and distributed by the NECC and the Affiliated Defendants (as defined below) and administered by a defendant healthcare provider.

12. For many of the Plaintiffs, each underwent a lumbar puncture (spinal tap) to determine the presence of meningitis or other infection. A lumbar puncture is performed in the lower back, in the lumbar region. During lumbar puncture, a needle is inserted between two lumbar bones (vertebrae) to remove a sample of cerebrospinal fluid — the fluid that surrounds the brain and spinal cord to protect a person from injury.

13. Plaintiff Gene Geary is a resident of the State of Ohio. He was administered a subject product at BKC PAIN SPECIALISTS, LLC 1065 Delaware Avenue, Marion, OH 43302 on September 17, 2012. After the injection with the contaminated product(s), he underwent a lumbar puncture to test for the presence of meningitis or other infection. He had continuing headaches, sharp pains, and spinal pains as a result of the stated product administration. He is not married.

14. Plaintiff Ricky Lane is a resident of the State of Ohio, and was administered a subject product at Marion Pain Clinic 1065 Delaware Avenue, Marion, OH 43302 in August and September of 2012. After the injection with the contaminated product(s), he underwent a lumbar puncture to test for the presence of meningitis or other infection. He alleges ongoing pain including numbness and headaches. His spouse is Susan Lane.

15. Plaintiff Teresa Lawrence is a resident of the State of Ohio, and was administered recalled products while a patient at Marion Pain Clinic 1065 Delaware Avenue, Marion, OH

43302 from September 6 through 20, 2012. After the injection with the contaminated product(s), she underwent a lumbar puncture to test for the presence of meningitis or other infection. She is still experiencing pain as a result thereof.

16. Plaintiff Tracey Layne is a resident of the State of Ohio and was administered recalled products while a patient at BKC PAIN SPECIALISTS, LLC 1065 Delaware Avenue, Marion, OH 43302 in September and October of 2012. After the injection with the contaminated product(s), she underwent a lumbar puncture to test for the presence of meningitis or other infection. She is still experiencing pain as a result thereof.

17. Plaintiff Dawn Miller is a resident of the State of Ohio and was administered recalled products while a patient at BKC PAIN SPECIALISTS, LLC 1065 Delaware Avenue, Marion, OH 43302 in August of 2012. After the injection with the contaminated product(s), she underwent a lumbar puncture to test for the presence of meningitis or other infection. She is still experiencing pain as a result thereof.

18. Plaintiff Clarence Mullins is a resident of the State of Ohio and was administered recalled products while a patient at BKC PAIN SPECIALISTS, LLC 1065 Delaware Avenue, Marion, OH 43302 in July, August and September of 2012. After the injection with the contaminated product(s), he underwent a lumbar puncture to test for the presence of meningitis or other infection. He is still experiencing pain as a result thereof.

19. Plaintiff Pauline Parks is a resident of the State of Ohio and was administered recalled products while a patient at BKC PAIN SPECIALISTS, LLC 1065 Delaware Avenue, Marion, OH 43302 in September of 2012. After the injection with the contaminated product(s), she underwent a lumbar puncture to test for the presence of meningitis or other infection. She is still experiencing pain as a result thereof.

20. Plaintiff Chester Smith is a resident of the State of Ohio and was administered recalled products while a patient at Cincinnati Eye Institute, Cincinnati, Ohio in in May of 2012. After the injection with the contaminated product(s), developed tuberculosis of the eye with diminished eyesight and partial blindness. He is still experiencing pain and blindness as a result thereof. Linda Sue Smith is his spouse.

21. Plaintiff Lisa Snyder -Blevins is a resident of the State of Ohio and was administered recalled products while a patient at BKC Pain Specialists, in Marion Ohio in July of 2012. After the injection with the contaminated product(s), she underwent a lumbar puncture. She is still experiencing pain as a result thereof.

22. Plaintiff Cindy Wallace is a resident of the State of Ohio and was administered recalled products while a patient at Interventional Pain and Wellness Center, 1212 Garfield Ave., Suite 300, Parkersburg, WV 26101 in June and September of 2012. After the injection with the contaminated product(s), she developed an infection in her hip. She is still experiencing pain as a result thereof.

23. Plaintiff William Kight is a resident of the State of Ohio and was administered recalled products while a patient at BKC Pain Specialists, in Marion Ohio in July and September of 2012. After the injection with the contaminated product(s), he underwent a MRI. He is still experiencing pain as a result thereof. His spouse is Mary Kight.

24. Plaintiff Glenn Welch is a resident of the State of Ohio and was administered recalled products while a patient at BKC Pain Specialists, in Marion Ohio in July of 2012. After the injection with the contaminated product(s), he underwent a lumbar puncture. He is still experiencing pain as a result thereof. His spouse is Dawn Welch.

25. Plaintiff Kelly Williams is a resident of the State of Ohio and was administered recalled products while a patient at BKC Pain Specialists, in Marion Ohio in July, August and September of 2012. After the injection with the contaminated product(s), she underwent a lumbar puncture. She is still experiencing pain as a result thereof.

Defendants

26. Defendant Liberty Industries, Inc. is a Connecticut corporation with its principal place of business at 133 Commerce Street, East Berlin, Connecticut 06023. Liberty designs, manufactures, distributes, and installs cleanrooms and contamination control supplies both in the United States and worldwide. Liberty manufactured, constructed, installed, and/or designed all NECC and Ameridose cleanrooms at the Framingham, Massachusetts facility. The cleanrooms manufactured, constructed, installed and/or designed for NECC and/or Ameridose contained defects that made them unsuitable for their intended use and were a direct and proximate cause of injury to Plaintiffs.

27. Defendant UniFirst Corporation is a corporation duly organized and existing under and by virtue of the laws of the State of Ohio, as noted above. It may also do business as UniClean Cleanroom Services, and shall be referred to as "UniFirst." UniClean is a division of UniFirst. UniFirst's corporate mission is to be recognized as the quality leader in the cleaning and garment industry. UniFirst also represents that its services will "improve the safety and cleanliness" of a business facility when hired to perform services there. UniFirst at all material times contracted with NECC to provide cleaning services, including cleaning the "cleanrooms" used to manufacture and/or compound drugs, including NECC Contaminated Drugs.

28. The CDC identified the following facilities which received recalled lots of MPA and other products from NECC in the State of Ohio:

Facility Name	
BKC PAIN SPECIALISTS, LLC Principal place of business located at: 1065 Delaware Ave., Ste. A Marion, OH 43302 Registered Agent Address: Mark A. Peterson 2 Miranova Place, Ste. 330 Columbus, OH 43215	
CINCINNATI PAIN MANAGEMENT Principal place of business located at: 8261 Cornell Rd., Ste. 630 Cincinnati, OH 45249	
MARION PAIN CLINIC Principal place of business located at: 1199 Delaware Ave. Marion, OH 43302	
ORTHO-SPINE REHABILITATION CENTER, INC. Principal place of business located at: 7211 Sawmill Road, Ste. 101 Dublin, OH 43016 Registered Agent Address: David L. Humphrey 7658 Slate Ridge Blvd. Reynoldsburg, OH 43068	

III. FACTUAL BACKGROUND

A. The Conigliaro Family Businesses.

1. Conigliaro Industries' Recycling Plant.

29. In 1990, Gregory Conigliaro opened Conigliaro Engineering in an old industrial building on Waverly Street in Framingham, Massachusetts. In 1991, the company incorporated under the new name Conigliaro Industries, Inc. and began recycling plastic, metal, glass, and paper. It made money by converting detergent bottles into recycling bins, molded Styrofoam lunch trays into flower pots, and plastic computer casings into pothole filler.

30. Early on, Gregory Conigliaro branched out into real estate, starting GDC Holdings Inc. and GDC Properties Management LLC.

31. In April 2003, Conigliaro Industries opened the first U.S. commercial plant that shreds and recycles mattresses, including polyurethane foam parts. The mattress recycling operation was planned and developed by Tony Conigliaro, the Vice President of Engineering and Gregory's father. The company built a 2,500 square foot mattress shredding facility located next to its 90,000 square foot plant on a seven acre parcel in Framingham. The company also earmarked another 5,000 square feet of its main factory space for the venture and utilized its 30 docks for the operation.

32. Old used mattresses from schools, prisons, and hospitals are put through a giant shredder that separates the polyurethane foam from the springs and wood frame and bales the foam. Gregory Conigliaro claimed that the company (Nationwide Foam, Inc., 703 Waverly Street, Framingham, Massachusetts) could recycle mattresses at the rate of one each minute.

33. Today, Conigliaro Industries touts itself as a pioneer in the field of "Total Recycling" and recycles over 150 different materials, including rubber, plastics, and metal. The business operates out of an 88,000 square foot facility located at 701 Waverly Street, in the large Framingham complex owned by Gregory Conigliaro's real estate companies, GDC Holdings Inc. and/or GDC Properties Management LLC. The Framingham Board of Health has received a number of complaints about the mounding trash piles tucked behind the Waverly Street strip mall.

Figure 1: Trash behind 701 Waverly Street[1]

Figure 2: Google Earth image of 701 Waverly St.

[1] "Sterility Found Lacking at Drug Site in Outbreak," N.Y. TIMES (Oct. 23, 2012) (available at http://www.nytimes.com/2012/10/24/health/sterility-found-lacking-at-drug-site-in-meningitis-outbreak.html?pagewanted=all&_r=0),.

2. Gregory Conigliaro, Barry Cadden, and Douglas Conigliaro founded NECC.

34. In 1998, well after the Conigliaro recycling facility and real estate companies were up and running, the Conigliaro family branched out into pharmaceutical compounding. Gregory Conigliaro's sister, Lisa Conigliaro Cadden, and her husband, Barry Cadden, were both pharmacists. Gregory Conigliaro and Barry Cadden co-founded New England Compounding Pharmacy, Inc., known as New England Compounding Center ("NECC"). NECC opened in the same Waverly Street building that housed the recycling plant and real estate businesses. Its front door is immediately next to the front door to Nationwide Foam.

35. Another Conigliaro brother, Dr. Douglas Conigliaro, was an anesthesiologist with substantial litigation in his past. He allegedly punctured a 64-year-old woman's spine during a 1995 operation to insert a pump to deliver painkillers. The woman became paralyzed and died two years later. The suit ultimately settled for $1 million and Douglas Conigliaro was fined $10,000 by the Florida state medical board.

36. Douglas Conigliaro's wife, Carla Conigliaro initially owned sixty-five percent (65%) of NECC. Carla Conigliaro (a nurse) was originally listed as the company's president. Douglas Conigliaro was personally involved with NECC from the beginning and continued to be involved until NECC shut its doors. Because of his previous legal troubles, he was careful to conceal his involvement. He also ordered others at NECC and the Affiliated Defendants to conceal, his involvement.

37. Barry Cadden ran NECC, typically wearing scrubs to work. Cadden held positions as the President, Chief Pharmacist, and Director of NECC.

38. Gregory Conigliaro provided financial advice and usually wore a shirt and tie. Lisa Conigliaro Cadden was a board member and worked as a pharmacist at NECC.

39. According to former employees, Douglas Conigliaro was heavily involved in the day-to-day operations of NECC and Ameridose, though employees were told not to mention his involvement to potential clients or customers.

3. Medical Sales Management.

40. In or around 2002, the Conigliaros opened another company in the same Framingham building, called Medical Sales Management Inc. ("MSM"). MSM, led by Douglas Conigliaro, provided advertising and marketing services for NECC. As the sales arm for NECC and Ameridose, MSM promoted the compounding business at trade shows across the country, and its sales force aggressively worked the phones, cold-calling new customers and reaching out to existing ones. It also helped manage the company's computer operations.

41. Later, MSM provided the same services to Ameridose.

4. Ameridose.

42. In 2006, Gregory Conigliaro and Barry Cadden launched Ameridose, LLC ("Ameridose"), originally located in the same Framingham building. Former employees say the Conigliaro family found a new opportunity, selling a much-needed service to hospitals: prefilling syringes and breaking down vats of liquid medications into smaller intravenous bags for individual treatments. Historically hospitals did much of that work themselves. But new federal regulations required hospitals to go through more elaborate steps to handle sterile preparations, making it more costly and complicated.

43. Unlike NECC, Ameridose has a manufacturing license from the FDA, allowing it to ship medications in bulk without obtaining individual prescriptions.

44. Ameridose would later lease additional office space in Westborough, Massachusetts. This additional space was, in part, to accommodate the growing MSM sales force. Ameridose officially changed its address to the Westborough facility in 2011.

45. In 2008, Ameridose had 50 employees. As of 2012, that number had skyrocketed to 400. Ameridose is also currently under investigation for deficient and harmful product compounding and sterilization practices.

5. Alaunus Pharmaceutical.

46. In 2009, Gregory Conigliaro and Barry Cadden founded yet another company, Alaunus Pharmaceutical LLC. Alaunus identifies, develops, and markets generic pharmaceutical products to physicians and pharmacies throughout the United States. It has several Abbreviated New Drug Applications on file with the FDA though apparently no approved products. Alaunus is located at 687 Waverly Street, in the same office park as NECC and the recycling facility.

47. Figure 3: Waverly Business Center Sign[2]

B. Background on Compounding Pharmacies.

[2] "Merging of families fueled business linked to meningitis outbreak," BOSTON GLOBE (Oct. 18, 2012) (available at http://www.nytimes.com/2012/10/24/health/sterility-found-lacking-at-drug-site-in-meningitis-outbreak.html?pagewanted=all&_r=0).

48. According to the FDA, traditional compounding is the extemporaneous combining, mixing, or altering of ingredients by a pharmacist in response to a physician's prescription to create a medication tailored to the specialized needs of an individual patient. Traditional compounding typically is used to prepare medications that are not available commercially, such as a drug for a patient who is allergic to an ingredient in a mass-produced product, or diluted dosages for children.

49. NECC's webpage claimed compounding allows doctors to prescribe prescription drugs that are "no longer manufactured, persistently backordered because of production shortages, not commercially available in the dosage form the patient needs (e.g., preservative free)."

50. In Massachusetts, compounding pharmacies must have a prescription from an individual patient in order to create a drug.

51. Compounding pharmacies generally follow testing guidelines established by the U.S. Pharmacopeia (USP), a nonprofit private group that develops standards of drug quality. According to an industry group, the International Academy of Compounding Pharmacists, adherence to the USP standards is expected. Some Massachusetts compounding pharmacies, including Microtest Laboratories, typically test more than the number of samples required by the USP standards to confirm sterility.

52. Compounding industry standards were created for pharmacists making small batches of medicines for individuals, not for the commercial production of large batches.

C. The Risks of Pharmacy Compounding.

53. The serious risks of pharmacy compounding were the subject of considerable public discussion in the pharmacy community and the medical community before the subject meningitis outbreak.

54. In 2002, the CDC published a report regarding at least two cases of fungal meningitis arising from contaminated medication used in epidural injections. The report concluded that "purchasers of pharmaceuticals should determine if supplies are provided from a compounding pharmacy that . . . follows appropriate measures to ensure that injectable products are free of contamination."

55. On March 24, 2005, USA Today published a front page article with the following headline: "Safety concerns grow over pharmacy-mixed drugs." That article discussed growing concern over the fact that drugs produced in bulk by compounding pharmacies are not FDA approved and are not subject to the same oversight as drugs produced by pharmaceutical companies.

56. In 2006, the FDA conducted a survey of compounded drug products. They collected thirty-six samples from compounding pharmacies across the United States during unannounced visits. Twelve of the 36 samples (33%) failed analytical testing. The FDA survey concluded "poor quality compounded drugs are a serious public health concern, as improperly compounded products have been linked to grave adverse events, including deaths."

57. In May 2007, the FDA published an article titled: "The Special Risks of Pharmacy Compounding." That article highlighted numerous adverse events involving compounded products. It also warned of the emergence of large scale compounding operations that were clearly operating outside the bounds of traditional compounding practice.

58. In 2010, the FDA posted an educational video on YouTube regarding concerns over the quality of compounded drugs.

59. On November 5, 2010, the American Society of Anesthesiologists, the American Society of Health-System Pharmacists ("ASHP") and other medical societies published a joint

report regarding drug shortages. That report included an article written by the ASHP stating as follows:

> Compounding pharmacies have also pursued the production of drugs that are in short supply. Caution is warranted because preparations from these pharmacies may not meet applicable state or federal standards (e.g., United States Pharmacopeia chapter 797 or FDA labeling requirements). The sources of raw materials used by compounding pharmacies have been questioned, and apparent lapses in quality control have resulted in serious patient injury, including death.
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> . . .
>
> Compounding pharmacies may also present patient risks; several deaths have been associated with improperly sterilized compounded products.

60. In May 2012, the CDC published a report regarding fungal infections arising from medications obtained from a compounding pharmacy. That report advised that "contamination of compounded sterile preparations has caused outbreaks. Since 1990, FDA has learned of approximately 200 adverse events associated with 71 compounded products."

D. Meningitis and related conditions.

61. Meningitis is an infection of the membranes covering the brain and spinal cord (meninges). Primary symptoms include: fever, chills, altered mental status, nausea, vomiting, and sensitivity to light (photophobia), severe headache, and neck stiffness. Meningitis is typically diagnosed by lumbar puncture (spinal tap) that collects spinal fluid (cerebrospinal fluid). The fluid is then tested to determine the infection's exact cause for an appropriate course of treatment. When a lumbar puncture is not possible, a diagnosis may be presumed based on the constellation of symptoms. Complications and risks from meningitis include: brain damage, buildup of fluid between the skull and brain (subdural effusion), hearing loss, hydrocephalus, and seizures.

62. Meningitis can be caused by several factors including bacteria, viruses, and fungus. Fungal meningitis is rare and people with weak immune systems are at a higher risk of contraction.

63. Meningitis is an infection that usually spreads through the blood to the spinal cord. It is caused by the introduction of a bacteria, virus, or fungus into the central nervous system or from an infected body site infection next to the central nervous system. Primary symptoms include: fever, altered mental status, nausea, vomiting, sensitivity to light (photophobia), headache, and stiff neck. Death may result from fungal meningitis.

64. The typical incubation period for contracting fungal meningitis from a tainted steroid is one to four weeks after injection, though it can be far longer and symptoms can be mild in nature. As with any variety of meningitis, it is important to perform a lumbar puncture (spinal tap) to collect and test spinal fluid (cerebrospinal fluid) and determine the exact type of fungus for an appropriate course of treatment. Appropriate laboratory tests may vary depending on the type of fungus suspected. Treatment of fungal meningitis typically requires long courses of high dose antifungal medications but treatment length can vary depending on the state of the immune system and type of fungus.

E. The Outbreak and Its Aftermath.

65. On September 21, 2012, the CDC was notified by the Tennessee Department of Health ("TDH") of a patient with the onset of meningitis following an epidural steroid injection. It was later determined that the patient had fungal meningitis.

66. On September 24, 2012 the TDH notified the Massachusetts Department of Public Health ("MDPH") about a cluster of six fungal meningitis cases with symptoms that began between July 30 and September 18, 2012. These patients all received injections of preservative free MPA, compounded at NECC in Framingham, Massachusetts.

67. In September 2012, the TDH identified nine cases of fungal meningitis following injection of MPA, compounded at NECC. All nine patients had received one or more injections from three lots of MPA (lot numbers 05212012@68, 06292012@26, and 08102012@51).

F. FDA and MDPH Begin Investigating NECC.

68. The MDPH, Board of Registration in Pharmacy, and Bureau of Infectious Diseases convened a multi-agency meeting with the TDH, the CDC, the FDA, and NECC. At the demand of MDPH staff, Barry Cadden and Gregory Conigliaro provided documentation of facilities that received medications from three lots of MPA suspected as linked to the fungal infections. According to those lists, the suspected lots contained 17,676 doses and were distributed to more than 14,000 patients in 23 states.

69. On September 26, 2012 NECC recalled three lots of preservative-free MPA: Lot #05212012@68, BUD 11/17/2012; Lot #06292012@26, BUD 12/26/2012; and Lot #08102012@51, BUD 2/6/2013. Approximately 3,000 doses were quarantined or returned through recall. This meant that approximately 14,000 people received contaminated injections. NECC faxed the recall notices to the facilities that had received the contaminated lots beginning on September 26, 2012.

70. On the same day, the MDPH began its investigation of NECC's facility. When MDPH arrived at NECC, investigators found NECC employees cleaning compounding areas and conducting environmental testing. The investigators also detected signs of black contamination in the compounding areas.

71. Before arrival of investigators, NECC had terminated many of its staff. After September 26, 2012, the majority of NECC employees were no longer on site.

72. On October 1, 2012 MDPH and FDA began a joint investigation of NECC. Investigators were shown examples of MPA products that were labeled as patient-specific. But

NECC did not have individual prescriptions. Instead, it had lists of patients generated by clinical facilities and provided to NECC to obtain the product. NECC stated the list of names was considered to be an authorized prescription by the physician. This practice is not in accordance with Massachusetts regulations.

73. MDPH issued a formal Quarantine Notice pursuant to M.G.L. c. 94C §§13 and 189A, and M.G.L. c. 112 §§ 30 and 42A, in accordance with the CDC's epidemiological work. The Notice directs that all raw materials, all non-sterile and sterile products located at NECC used in the compounding of MPA and all inventory on the premises prepared for dispensing and stored at the pharmacy should be quarantined and not disposed of without MDPH's approval.

74. MDPH and FDA observed visible black particulate matter in sealed vials of purportedly sterile MPA returned to NECC. Inconsistencies in sterilization of processed materials were identified through review of NECC's records. The board voted to obtain a Voluntary Surrender of NECC's license or to initiate action to issue a Temporary Order of Summary Suspension.

G. NECC Surrenders Its Pharmacy License and Recalls All of Its Products.

75. On October 3, 2012 NECC surrendered its pharmacy license. It ceased all production and initiated recall of all MPA and other drug products prepared for injections in and around the spinal cord (known as intrathecal administration).

76. On October 5, 2012 MDPH and FDA investigators noted visible contaminants in additional sealed recalled vials of MPA. MDPH and FDA issued a nationwide alert to providers and facilities across the country, informing them about the particulate matter.

77. On October 6, 2012 NECC, in conjunction with the FDA, CDC, and Massachusetts Board of Registration in Pharmacy's investigation, recalled all products currently

in circulation that were compounded at and distributed from its facility in Framingham, Massachusetts "due to the potential risk of contamination."

78. In NECC's October 6, 2012, press release, NECC advised that it was "notifying its customers of this recall by fax[,]" and that "[c]linics, hospitals and healthcare providers that have the product which is being recalled should stop using the product immediately, retain and secure the product, and follow instructions contained in the fax notice."

H. FDA and Massachusetts Board of Pharmacy's Findings.

79. MDPH obtained documentary evidence (including photographs), reviewed and obtained copies of NECC Standard Operating Procedures, made observational findings, reviewed and obtained copies of all policies and procedures, reviewed batch records and interviewed NECC staff. The FDA conducted product testing and took environmental samples of various areas of the facility to test for contaminants.

80. From the beginning of their investigation, the MDPH and FDA identified "serious deficiencies and significant violations of pharmacy law and regulations that clearly placed the public's health and safety at risk." The FDA reported that it had detected fungal contamination by microscopic examination of particulate matter taken from a sealed vial of MPA collected from NECC. The FDA also noted that "foreign material" had also been observed in other vials produced by NECC that were collected by FDA during an inspection. FDA further stated that it was in the process of further identifying the fungal contaminant and conducting microbial testing.

I. MDPH's Preliminary Findings.

81. On October 23, 2012, the MDPH released its preliminary investigation findings. A copy of the report is attached as Exhibit A.

82. NECC distributed two of the recalled lots of MPA (preservative free) 80 MG/ML before receiving results of sterility testing. Lot 06292012@26 was prepared on June 29, 2012. Final sterility testing was completed on July 17, 2012. Two shipments of product were sent out before the final sterility tests results were received. Lot 08102012@51 was prepared on August 10, 2012. Final sterility testing was completed on August 28, 2012. At least eleven shipments of product were sent out before the final sterility test results were received. NECC's records claim that these sterility tests found no contamination, but the MDPH questioned whether NECC's sterility testing methods were adequate.

83. The MDPH observed visible black particulate matter in several recalled sealed vials of MPA from Lot 08102012@51.

84. NECC did not follow either the proper USP 797 autoclaving sterilization procedure or its own standards operating procedures. The MDPH noted NECC's systemic failure to keep products in the autoclave for the required minimum 20-minute sterilization period necessary to ensure product sterility.

85. MDPH found that NECC distributed large batches of compound "sterile" products directly to facilities apparently for general use rather than requiring a prescription for an individual patient, in violation of its state pharmacy license.

86. NECC did not have patient-specific prescriptions from an authorized practitioner when compounding and dispensing medication, as required by state law.

87. NECC did not conduct patient-specific medication history and drug utilization reviews, as required by regulations.

88. The clean rooms used to compound the drugs were not appropriately sealed, allowing contaminants to infiltrate the room, and exposing the drugs to contamination.

89. Powder hoods, intended to protect pharmacists from inhaling substances during medication preparation within the sterile compounding area were not thoroughly cleaned pursuant to USP 797 or pursuant to NECC standard operating procedures. Residual powder was visually observed, which could lead to contamination of compounded medications.

90. "Tacky mats" used to trap dirt, dust, and other potential contaminants from shoes prior to clean room entry were visibly soiled with debris, in violation of USP 797.

91. A leaky boiler next to the clean room created an environment susceptible to contaminant growth, including a pool of standing water.

J. FDA's Initial Findings and Form 483 Report.

92. On October 18, 2012, the FDA released definitive laboratory confirmation of the presences of fungal contaminants in sealed vials of MPA in a suspect lot prepared by NECC.

93. On October 26, 2012, the FDA released a copy of the FDA form 483 issued to NECC. The FDA issues a 483 at the end of an inspection when the investigators believe that they observed conditions or practices that indicate violations of the Food, Drug, and Cosmetic Act or attendant regulations. A copy of the report is attached as Exhibit B.

94. The FDA observed and has since confirmed contaminated products and listed a number of observations regarding conditions in the Clean Room 2 at NECC's Framingham facility.

95. During an October 2, 2012 inspection, the FDA observed that approximately 83 vials of a bin of 321 vials of MPA from Lot #08102012@51 (shipped between August 17, 2012 and September 25, 2012) to contain a greenish black foreign matter. Seventeen vials from the same bin contained white filamentous material.

96. The FDA's sterility analysis of a sample confirmed the presence of "viable microbial growth" in all of the 50 vials tested. One vial showed fungal morphological features.

97. The FDA reported that NECC's formula worksheets state that the raw materials used to create their drug products are sterile, NECC's pharmacy director told the FDA that NECC uses non-sterile active pharmaceutical ingredients (API) and non-sterile raw materials to formulate preservative free MPA, triamcinolone, and other injectable suspensions. The inspection confirmed that the labeling for the MPA API and other raw materials did not indicate that they were sterile.

98. NECC claimed that its "steam autoclave cycle" "sterilized" suspensions formulated with non-sterile materials. The FDA noted that NECC provided no documentation or evidence that this autoclave procedure worked. In fact, the FDA reported tarnish, condensation, and discoloration in the autoclaves. The FDA also observed puddles of water in the base of the autoclave chamber.

99. The FDA also reported that on at least 26 occasions between January 2012 and September 2012, NECC's internal environmental monitoring program recorded bacteria and mold in the clean rooms used to produce "sterile" drug products. This included at least 38 instances where the level of bacteria recorded was above the level where NECC was supposed to take action ("action level" or "action limit") and 18 instances where the level of mold reported was above NECC's action level. According to the FDA's director of manufacturing and product quality, an action limit is a threshold measurement of contamination "above what would typically be seen in a controlled sterile environment." Yet NECC took no action to investigate or correct this bacterial and mold contamination:

> There was no investigation conducted by the firm when levels exceeded their action limits and there was no identification of the isolates. No documented corrective actions were taken to remove the microbial contamination (bacteria and mold) from the facility.

100. Some of the petri dishes used to grow microbes present in environmental samples taken from windowsills, equipment, furniture, floors and other surfaces were "overflowing" with bacteria or fungi in sheets "very visible to the naked eye." The FDA also reported that samples taken from inside the hoods used for compounding (also inside the ostensibly clean rooms) between January and September 2012 showed at least eight instances of bacterial and/or mold contamination. NECC did not investigate this contamination, did not identify the types of mold or bacteria growing in their ostensibly sterile hoods, nor investigate the impact of this contamination on any of the purportedly sterile products made in the hoods on the days the samples were taken. "[NECC] has no evidence that any corrective actions were taken to prevent contamination of the sterile drug products."

101. The FDA also observed that a plastic and mattress recycling facility next door produced dust and other airborne contaminants. NECC's HVAC units on the roof were about 100 feet from the recycling facility. Inside NECC, the FDA observed that dark particulate and white, filamentous substances covered the louvers of an HVAC return located behind the autoclave in the clean room.

102. The FDA also observed that the air-conditioning in the clean rooms was turned off overnight. This is not typical for a clean room, as temperatures need to be kept constant to minimize microbial growth.

103. The FDA also observed that a boiler located within 30 feet of the entrance to one of the "Prep Room" was leaking water into puddles. The wet floor around the boiler was soiled with thick white debris and thick black granular material.

104. The mat at the entrance of the Prep Room was brown and soiled. In other words, it was filthy.

105. The FDA also observed cloudy discoloration on the barrier facing the ISO 6 Clean Room and metal surfaces of the pass through in the wall to the ISO 6 Clean Room. The metal ledge within the clean room contained reddish-brown and cloudy substances. And there were "dark, hair like discoloration" along the gasket and crevices located at the bottom edge of the closed pass through installed within the wall of the ISO 6 Clean Room. NECC used ISO 6 Clean Room to formulate and fill sterile preparation, including MPA.

K. The Investigation Grows, Covering Other Drugs and Related Corporate Entities.

1. MDPH Shuts Down Ameridose and Suspends Insiders' Pharmacy Licenses.

106. On October 8, 2012, at the MDPH and FDA's insistence, Barry Cadden, Glenn Chin, and Lisa Cadden, leaders at NECC, agreed to stop practicing as pharmacists until the investigation was complete. On October 10, 2012 MDPH asked Ameridose and Alaunus Pharmaceuticals to cease all operations, including dispensing, manufacturing, or distributing any products. MDPH demanded that Barry Cadden immediately resign as manager, director and from any other management position at NECC, or Ameridose.

2. FDA Confirms Other NECC Products Are Contaminated.

107. On October 15, 2012 the FDA issued an advisory that a patient may have acquired fungal meningitis from a different steroid injection, triamcinolone acetonide. In addition, the FDA reported a transplant patient with aspergillus funigatus infection who receiv

108. ed NECC cardioplegic solution during surgery. MDPH asked Massachusetts providers to contact any patients who received any injectable product, including opthalmis drugs or cardioplegia solutions prepared by NECC after May 21, 2012.

109. On October 18, 2012 the FDA confirmed the presence of fungal contaminates in sealed vials of MPA in a suspect lot prepared by NECC. The FDA also collects samples from sealed vials of completed product at Ameridose.

3. Board of Pharmacy Revokes Cadden, Chin and Conigliaro Pharmacy Licenses.

110. On October 22, 2012 *t*he Board of Pharmacy and MDPH announced that Barry J. Cadden, Glenn A Chin, and Lisa Conigliaro Cadden are prevented from practicing as pharmacists, that it asked all three to surrender their pharmacist licenses immediately, and that if they did not voluntarily comply their license would be permanently revoked. According to MDPH, "[i]f the three pharmacists and NECC do not comply, the Board authorized staff to proceed with permanent revocation."

L. FDA and MDPH Investigate Ameridose and Alaunus Pharmaceuticals.

111. On October 19, 2012 investigators at MDPH and FDA scrutinized the business practices of Alaunus Pharmaceuticals and potential for inappropriate distribution of NECC or Ameridose products.

112. On October 31, 2012 Ameridose announced a recall of all of its products. The company sells more than 2,200 drugs in syringes (injectable and oral) and intravenous medicine bags.

113. Dr. Janet Woodcock, the director of the Center for Drug Evaluation and Research at the FDA, said in a telephone interview that the company offered to recall all of its products after federal officials shared the results of their inspection, which found fault with some of its sterility "assurances."

114. On November 1, 2012 the FDA and CDC found bacterial contamination in two other drugs made by NECC, preservative-free betamethasone (a steroid used to help back pain)

and cardioplegia solution (used during heart surgery). The FDA found bacteria in three separate batches of betamethasone. Earlier tests had found fungal contamination in the cardioplegia solution. These finding "reinforce the FDA's concern about the lack of sterility in products produced at NECC's compounding facility and serve to underscore that hospitals, clinics, and health care providers should not use any NECC-supplied products."

1. FDA Confirms Ameridose's Products Are Contaminated.

115. On November 9, 2012, the FDA released a report describing the results of its inspection of the Ameridose facilities at 701 and 705 Flanders Road in Westborough, MA. The dates of inspection included October 10-12, October 15-16, October 18-19, October 22-23, October 26, and November 6-9. A copy of the report is attached as Exhibit C.

116. The report made 15 observations. Two of these observations were "repeat items" included in an FDA form 483 report issued to Ameridose on August 6, 2008. Namely, that (1) Ameridose does not test the potency of its final drug products before releasing them for distribution (despite receiving 33 complaints about lack of effect) and (2) Ameridose does not test final units of finished product lots for sterility and the presence of bacterial endotoxin.

117. The FDA observed that Ameridose failed to investigate microbial contamination observed at least fifty three (53) times during sterility testing of stock solutions intended to be used in the manufacture of sterile injectable products, including lots of Fentanyl, Ropivacain, and morphine. Multiple lots of purportedly sterile injectable drug products were compounded, prepared, sold, and distributed from these contaminated lots.

118. The FDA saw "no documented evidence" to suggest that Ameridose ever conducted a health hazard investigation of these 53 instances of contamination. Ameridose claimed that these sterility failures were attributed to contamination during the sterility testing

itself (as opposed to during the manufacture of the product); the FDA noted that there was "no data to support" this claim.

119. Ameridose regularly disregarded sterility test results that were "positive," meaning that test results showed products were contaminated and/or not sterile. Ameridose assumed that any positive result was "inconclusive" or "suspect" and re-ran the test. This re-testing often revealed more non-sterile units than the original test. Ameridose did nothing to identify the source of the contamination nor subculture the bacteria to determine its identity.

120. In 2012, forty-five (45) environmental microbiological contaminants, bacterial and mold, were found in "critical areas," including instances of employees' presumably uncovered fingers inside on the hoods and controlled manufacturing areas during the manufacture of purportedly sterile drug products. There is no evidence that Ameridose took any steps to assess the potential quality impact of these potential contaminates. On at least one occasion, Ameridose "re-filtered" sterile stock solutions involved in the sterility failure and then released the final drug products for patient use.

121. Ameridose received at least 29 adverse event reports associated with its products. These ranged from reports of low potency, post-partum hemorrhaging, over-sedation, respiratory distress, and lack of effect. Ameridose did not report any of these adverse events to the FDA, as required by law. Instead, Ameridose called these "patient responses" or "non-complaints" and did not investigate or failed to investigate what the FDA called "a trend of complaints."

122. The FDA also observed visible indications of deficient manufacturing conditions. Gowns, eye-protection, and gloves worn by employees were not sterile and were reused multiple times before being sent for cleaning. Ameridose failed to perform environmental monitoring of the hoods used to manufacture products. "Penetrating leaks" were observed in the roof above the

clean room; Ameridose used totes to catch the streaming rain water. Walls in a room used to prepare purportedly sterile drug products were cracked, corroded, and covered with a sticky material. "Brownish structures," "whitish, opaque structures," rust, broken glass, "foreign material" and "thick residues" that were orange, brown, and green were found in and around the metal hoods used to prepare drug products. All of these hoods were indicated to be "clean and available for processing."

123. Ameridose did not evaluate any alarms reported by their air handling system.

124. Perhaps most disturbingly, the FDA reported insect infestations within 3-10 feet of the controlled area where sterile products were made. And at least one bird flew through an area where sterile finished product is packaged and stored during the FDA's investigation.

M. Criminal and Congressional Investigations.

125. The Department of Justice and the Commonwealth of Massachusetts have announced that they are pursuing criminal investigations of NECC's practices. Other States' Attorney Generals are also pursuing criminal investigations, including Michigan's, the state that has the most reported deaths and illnesses linked to NECC's Contaminated Drugs.

126. The U.S. House of Representatives Energy and Commerce Committee is also investigating the outbreak; in particular, the history of investigations and operation at NECC and other companies Barry Cadden was affiliated with that were at any point involved in the production, sale, and/or distribution of drug products. On October 11, 2012, the Committee wrote to Barry Cadden individually to request that NECC preserve all relevant documents and communications and that NECC make arrangements with Committee staff to testify before the Committee before October 18, 2012. Neither Cadden nor anyone else from NECC made themselves available to brief the committee.

127. On October, 22, 2012, the Committee asked Cadden to provide documents from January 1, 2002 through the present , including:

> All documents containing communications referring to relating to any license or inspection of the NECC, Ameridose, and/or Alaunus that [Cadden] sent or received using a personal email account;
>
> All documents containing communications referring or relating to the scope of business conducted by the NECC, Ameridose, and/or Alaunus that you sent or received using a personal email account;
>
> All documents containing communications referring or relating to any safety and/or quality issue related to any product produced, sold, and/or distributed by NECC, Ameridose, and/or Alaunus that you sent or received using a personal email account.

128. On November 14, 2012, the Committee held a hearing, titled "The Fungal Meningitis Outbreak: Could It Have Been Prevented?" Barry Cadden appeared, but repeatedly asserted his Fifth Amendment right against self-incrimination and did not answer any of the Committee's substantive questions.

N. Subsequent Litigation.

129. Lawsuits alleging death or injury based on contaminated MPA and other contaminated drugs have been filed around the country. On February 12, 2013, the Judicial Panel on Multidistrict Litigation issued an order under 28 U.S.C. § 1407 transferring various federal court proceedings to the United States District Court for the District of Massachusetts for coordinated pretrial proceedings.

O. Current Case Counts.

130. As of November 3, 2013, the CDC reports 751 cases of fungal meningitis, stroke due to presumed fungal meningitis, or other central nervous system-related infection meeting the outbreak case definition, in addition to paraspinal/spinal joint infections and peripheral joint infections (e.g., knee, hip, shoulder, and elbow). The CDC reports cases in Florida, Georgia,

Idaho, Illinois, Indiana, Maryland, Michigan, Minnesota, New Hampshire, New Jersey, New York, North Carolina, Ohio, Pennsylvania, Rhode Island, South Carolina, Tennessee, Texas, and Virginia. Of these 751 reported cases of fungal meningitis, at least 64 people have died (in nine different states). The CDC estimates that at least 14,000 patients were administered injections from just the three recalled lots of methylprednisolone acetate.

IV. FACTUAL ALLEGATIONS

A. Defendant Liberty Industries, Inc.

131. Liberty is a designer, manufacturer, distributor and installer of cleanrooms and contamination control supplies both in the United States and worldwide.

132. In 2005, 2006 and 2008, Liberty manufactured, constructed, installed, and/or designed an ISO Class 7, ISO Class 6, and an ISO Class 5 cleanrooms ("the Cleanrooms"), respectively, for NECC and/or Ameridose at the Framingham, Massachusetts facility.

133. Upon information and belief, subsequent room additions, rework or repair (warranty or otherwise), and/or system upgrades, done by Liberty, took place within each of these Cleanrooms after certification had been issued.

134. The Cleanrooms manufactured, constructed, installed and/or designed for NECC/Ameridose contained defects that made them unsuitable for their intended use. Liberty owed a duty to Plaintiffs, to manufacture, construct, install, and/or design the NECC/Ameridose Cleanrooms in such a manner as to prevent the contamination of pharmaceuticals compounded within them.

135. Liberty knew, or reasonably should have known, that the Cleanrooms were defective upon certifying them ready to use and/or upon inspecting the premises after certification and/or upon subsequent addition, rework or repair of the Cleanrooms.

136. Upon further information and belief, one or more of the Cleanrooms was designed with, manufactured, constructed and/or had installed faulty ceiling grids and/or used improper materials in addition to other deficiencies creating a cleanroom environment prone to pressure inconsistencies, water damage and other failings that would disrupt or destroy the cleanliness of the Cleanrooms and making them susceptible to contamination.

137. Upon information and belief, on numerous occasions, NECC requested and was denied repair of Liberty's defective work. In at least one cleanroom designed and installed by Liberty, a large opening in the wall provided access to a conveyor belt covered only with hanging vinyl slats. This opening provided a means of potential contamination and made it difficult to maintain the required negative air pressure.

138. Further, upon information and belief, Liberty had actual and/or constructive knowledge of the deficiencies in the design, manufacture, construction, and installation of the Cleanrooms, such that products compounded within them were subject to contamination.

139. One or more of the Cleanrooms were used to compound the NECC Contaminated Drugs administered to Plaintiffs.

140. The defective manufacture, construction, installation, and/or design of the Cleanrooms, and Liberty's failure to remedy the defects despite its actual and/or constructive knowledge of those deficiencies, caused Plaintiffs to suffer damages, including, but not limited to, expenses associated with the treatment of fungal meningitis and other illnesses. The defects were the direct, proximate, and foreseeable cause of damages incurred by Plaintiffs.

141. Had Liberty exercised its duty to exercise reasonable conduct by properly manufacturing, designing, and certifying the Cleanrooms, Plaintiffs would not have suffered the damages complained of herein.

B. Defendant UniFirst Corporation.

142. UniClean Cleanroom Services ("UniClean") is a division of Defendant UniFirst Corporation. Hereafter the entity shall be referred to as "UniFirst." UniFirst holds itself out as a service provider delivering value-added services and products to, among other industries, the medical device, pharmaceutical, and other industries that utilize cleanroom controlled environments. UniFirst represents that it offers comprehensive cleanroom cleaning and maintenance programs to help ensure that facilities are operating within specified classification goals.

143. UniFirst itself and/or through UniClean, touts its expertise to companies like NECC and Ameridose. UniFirst knows that particulates in cleanrooms are deposited onto surfaces such as floors, walls, work surfaces and machinery, and that these particulates may cause increases in manufacturing and product compounding reject rates. UniFirst, its agents, employees, representatives, and UniClean workers have, for many years, had actual knowledge that visible and non-visible particulate loads can also lead to product contamination safety concerns for end users. In its marketing materials Unifirst acknowledges that to reduce these risks, it is imperative that an effective cleanroom cleaning program be implemented and maintained. UniFirst claims to follow stringent cleaning procedures and claims to employ highly-trained technicians as key components in eliminating such contamination threats.

144. At all times mentioned herein and material hereto, UniFirst held itself and its agents, servants, workers, representatives, personnel, and employees out to be skillful and qualified to deliver quality services and products and through the highest standards. Indeed, UniFirst itself and/or UniClean, represents that it is an ISO 9001: 2008 registered company offering services that include sterile and non-sterile garment services, and contamination control including cleanroom cleaning, fogging and environmental monitoring, among other services.

145. UniFirst recognizes the dangers associated with contaminated cleanrooms. In the company's own marketing materials, it acknowledges that "80% of the dirt and grime that enters your building is tracked in on the shoes of employees and visitors." UniFirst knows that any contract for services or products entered into with any company such as NECC or Ameridose has a direct benefit for customers, who are the intended beneficiaries of such contracts. For example, UniFirst has stated on its website and in marketing materials that over 70% of customers say that a poorly maintained facility "is enough reason not to patronize a business again," and that by hiring UniFirst, a company's "business image will remain spotless, and your customers and employees will know you care."

146. UniFirst markets its products and services aggressively, and represents that, among other things, "To help with your infection control efforts, UniFirst delivers fresh mops and wipers and picks up your soiled ones on a regular schedule. We maintain inventory, perform hygienic laundering, and replace any worn out items."

147. UniFirst entered into a Contamination Control Service Agreement ("CCSA") with NECC on October 7, 2008, and renewed it thereafter, such that a contract existed in calendar years 2011 and 2012.

148. According to the terms of the CCSA and later iterations, UniFirst agreed to furnish services with supporting materials necessary for the performance of its duties, which expressly included cleaning each Cleanroom at the NECC facilities. UniFirst's duties were outlined in a Service Schedule attached and incorporated into the CCSA first signed and therafter in force and effect. UniFirst's duties included cleaning and sanitizing each anteroom and cleanroom. The areas to be cleaned and sanitized by UniFirst employees included but were not

limited to the floors, ceilings, and hoods of each room. UniFirst agreed to a triple decontamination process for each room, using products provided by UniFirst.

149. UniFirst agreed that, among other things, it would specifically provide its staff with cleanroom training and training regarding NECC's Standard Operating Procedures.

150. UniFirst performed services and sold products to NECC each month, from calendar year 2010 through September 2012, and UniFirst invoiced NECC for services rendered.

151. During the stated time frame, UniFirst failed to meets its own written standards in performing its contractual duties, allowing the contamination of the cleanrooms UniFirst was entrusted to clean in the following ways: (A) UniFirst employees, contractors and/or representatives, including those within the UniClean division, entered the NECC facilities (including the anterooms) in street clothes, without donning sterile or contaminant-free such as shoe covers, hair caps, coveralls, and gloves that were readily available at the NECC facilities; (B) UniFirst employees, contractors and/or representatives brought into the NECC anterooms and cleanrooms cleaning equipment, including mops, mop heads, sponges and buckets that had been moved through exterior environments, even though such equipment had not been sanitized by or cleaned appropriately, allowing contamination to occur throughout various parts of the NECC facility; and (C) UniFirst employees, contractors and/or representatives failed to clean or wipe shoes, boots and other footwear on floor mats used in the room entry process, thereby allowing contaminants into and throughout the NECC facility.

152. UniFirst had actual knowledge of the dangers of bacteria, mold and other microorganisms. UniFirst knew or should have known that such contaminants - if not eliminated - would expose patients and end use consumers such as Plaintiffs, to contamination of products produced by NECC in its cleanrooms.

153. UniFirst had actual knowledge of the very mold that was ultimately found in the NECC facility. In a "white paper" found on the www.unifirst.com website, UniFirst identifies aspergillus niger as a "mold" that grows when garments are contaminated. In the white paper UniFirst acknowledges that this mold represents one of the most common types of microorganism contaminants found in facilities like the NECC location.

154. Aspergillus niger was found or brought into in the NECC facility. UniFirst failed to perform the job it was hired to do.

155. As a result of failures and omissions, UniFirst (solely or in concert with NECC) negligently allowed contaminants such as aspergillus into every cleanroom where recalled products were made, composed, mixed, prepared, packaged and stored.

156. UniFirst, its agents, and employees knew or should have known of the dangers of allowing contaminants into the NECC facility, including its anterooms and cleanrooms. UniFirst did not conduct appropriate due diligence to follow its own policies and procedures, and failed to follow NECC policies and procedures when in that facility.

V. GENERAL ALLEGATIONS

157. As a direct and proximate result of NECC contaminated drugs and the Defendants' wrongful conduct, each Plaintiff has suffered and will continue to suffer serious physical injuries, in addition to pain, suffering, mental anguish, fright, shock, denial of social pleasures and enjoyments, embarrassment, humiliation and mortification, emotional distress, and further has incurred and will continue to incur medical and other expenses as a direct result of being exposed to NECC's Contaminated Drugs. Plaintiffs have suffered and will continue to suffer a loss of earning capacity.

158. Further, as a direct and proximate result of the NECC Contaminated Drugs, each spouse of each Plaintiff, lawfully married, suffered, and will continue to suffer, expenses related to the necessary medical care, treatment and services rendered to their spouse, the loss of services that they would have been provided had their spouse not been injured, and the loss of society and companionship and incidents of the marital relationship of which they have been deprived.

159. Further, as a direct and proximate result of the NECC Contaminated Drugs, each child and/or parent of each Plaintiff, suffered, and will continue to suffer, expenses related to the necessary medical care, treatment and services rendered to their loved one, the loss of services that their loved one would have provided them had their loved one not been injured and/or died, and the loss of society and companionship and incidents of the parent-child relationship of which they have been deprived.

CAUSES OF ACTION

COUNT I – NEGLIGENCE AND GROSS NEGLIGENCE (Against Liberty)

160. All allegations above are incorporated herein by reference.

161. Liberty owed Plaintiffs a duty to exercise reasonable care and to follow all applicable laws and standards during the manufacture, construction, installation, design, certification, and ongoing maintenance of the Cleanrooms in order to prevent or eliminate contamination of the Cleanrooms.

162. Liberty failed to exercise reasonable care in one or more of the following ways, so far as is presently known:

a. by failing to properly design and install the 2006 and 2008 Cleanroom ceiling grids, ceiling panels, light fixtures, and HEPA filtration modules;

b. by failing to properly design and install the 2006 and 2008 Cleanroom fire suppression system;

c. by failing to use proper materials in the construction of the ceiling of the Cleanrooms;

d. by failing to properly survey existing Cleanrooms and the facility as a whole to properly assess the risks associated with construction of subsequent Cleanrooms;

e. by failing to install a hard cap/hard ceiling over the ceiling of each Cleanroom to protect from contamination, despite Liberty's actual and/or constructive knowledge that the areas between the ceilings of the 2006 and 2008 Cleanrooms were prone to excessive contamination and water damage;

f. by prematurely certifying the 2006 and 2008 Cleanrooms;

g. by disrupting or otherwise breaching the cleanliness of the Cleanrooms through the installation of faulty ceiling grids, improper materials, and the conduct of subsequent work to each Cleanroom, resulting in or contributing to their contamination;

h. by failing to take reasonable steps to properly certify the Cleanrooms to ensure their cleanliness as required for their anticipated use;

i. by committing other violations as shall be revealed in discovery.

163. Each Plaintiff was a foreseeable victim of Liberty's negligence. Liberty knew that NECC and Ameridose were compounding drugs at their facility for national distribution and for use in patients such as Plaintiffs.

164. Liberty's wrongful conduct and negligence resulted in Plaintiffs' suffering serious physical injuries, distress and/or death.

165. As a direct and proximate result of Liberty's negligence, as well as that of Liberty's employees, agents, independent contractors, businesses, or others associated with and/or providing services, Plaintiffs' are entitled to recover all allowable elements of damages from Liberty in an amount that is just and appropriate to fully compensate Plaintiffs, decedent's estate, beneficiaries and/or next of kin for the serious physical injuries and/or wrongful deaths of Plaintiffs, plus interest and costs.

166. Liberty's conduct set out above constitutes gross negligence and a reckless disregard for human life and safety, thus warranting the imposition of punitive damages.

WHEREFORE, the Plaintiffs demand judgment against Liberty on Count I of this Complaint, in an amount that will justly compensate Plaintiffs for their damages, together with interest, costs and attorney fees incurred in this action, all within the jurisdictional limits of this Court.

COUNT II – NEGLIGENCE AND GROSS NEGLIGENCE
(Against UniFirst)

167. All allegations above are incorporated herein by reference.

168. UniFirst owed Plaintiffs a duty to exercise reasonable care to follow all applicable laws and standards, as well as NECC standard procedures, during the ongoing and regular maintenance and cleaning of the Cleanrooms in order to prevent or eliminate contamination of the Cleanrooms.

169. UniFirst knew or should have known that products produced, sold, and shipped by NECC required a sterile environment, and that such products would be used by end consumers such as Plaintiffs. UniFirst knew that end consumers of NECC products were the intended beneficiaries of the services to be rendered by UniFirst to NECC. UniFirst's knew that customers of a business like NECC expect and rely upon a clean and a safe environment for the

production of goods. UniFirst knew this for nearly four years before the recall of the NECC Contaminated Drugs.

170. UniFirst failed to exercise reasonable care in one or more of the following ways, so far as is presently known:

a) UniFirst employees, contractors and/or representatives, including those within the UniClean division, entered the Cleanrooms (including the anterooms) in street clothes, without donning sterile or contaminant-free clothing such as shoe covers, hair caps, coveralls, and gloves that were readily available at the NECC facilities, thereby failing to follow its own standards and policies;

b) UniFirst employees, contractors and/or representatives brought into the NECC anterooms and Cleanrooms cleaning equipment, including mops, mop heads, spongers, and buckets that had been moved through exterior environments, even though such equipment had not been sanitized or cleaned appropriately, allowing contamination to occur throughout various parts of the NECC facility, such actions failing to meet UniFirst's own standards as well as recognized industry standards;

c) UniFirst employees, contractors and/or representatives failed to clean or wipe footwear on mats used in the cleanroom entry process, thereby allowing contaminants into and throughout the Cleanrooms; and

d) UniFirst employees, agents, contractors and/or representatives were negligently supervised, and failed to adhere to and follow NECC standard operating procedures.

171. Each Plaintiff was a foreseeable victim of UniFirst's negligence. UniFirst knew that the Affiliated Defendants were compounding drugs at their facility for national distribution and for use in patients such as Plaintiffs.

172. The wrongful conduct and negligence of UniFirst resulted in Plaintiffs' suffering serious physical injuries, distress and/or death.

173. As a direct and proximate result of UniFirst's negligence, as well as that of UniFirst's employees, agents, independent contractors, businesses, or others associated with and/or providing services, Plaintiffs' are entitled to recover all allowable elements of damage from UniFirst in an amount that is just and appropriate to fully compensate Plaintiffs, decedent's estate, beneficiaries and/or next of kin for the serious physical injuries and/or wrongful deaths of Plaintiffs, plus interest and costs.

174. UniFirst's conduct set out above constitutes gross negligence and a reckless disregard for human life and safety, thus warranting the imposition of punitive damages.

WHEREFORE, the Plaintiffs demand judgment against UniFirst on Count II of this Complaint, in an amount that will justly compensate Plaintiffs for their damages, together with interest, costs and attorney fees incurred in this action, all within the jurisdictional limits of this Court.

COUNT III – LOSS OF CONSORIUM

(Against all Defendants)

175. All allegations above are incorporated herein by reference.

176. At all times material herein mentioned the following Plaintiffs are spouses: Linda Sue Smith (spouse of Chester Smith), Susan Lane (spouse of Ricky Lane), Dawn Welch (spouse

of Glenn Welch), Beverly Williams (spouse of Kelly Williams) and Mary Kight (spouse of William Kight).

177. As a further direct and proximate result of the Defendants' negligence, gross negligence and other culpable acts, omissions and activities set out above, each stated Plaintiff in the above paragraph suffered the loss of his or her spouse, services, companionship, society, and consortium, emotional distress and mental anguish, and will continue to suffer such loss and damages in the foreseeable future.

178. Each stated Plaintiff also has incurred and will incur expenses related to obtaining medical treatment and care for his or her spouse's injuries.

WHEREFORE, the stated Plaintiffs demand judgment against Defendants, jointly and severally, on each count of Complaint, in an amount that will justly compensate for the damages, together with interest, costs and attorney fees incurred in this action, all within the jurisdictional limits of this Court.

COUNT IV – PUNITIVE DAMAGES
(Against all Defendants)

179. All allegations above are incorporated herein by reference.

180. The above described acts and omissions on the part of the Defendants were reckless and intentional. Defendants were aware of, but consciously disregarded, a substantial and unjustifiable risk of such a nature that their disregard constitutes a gross deviation from the standard of care that an ordinary person would exercise under all the circumstances. Plaintiffs therefore are entitled to an award of punitive damages against the Defendants.

WHEREFORE, the Plaintiffs demand judgment against Defendants, jointly and severally, on all counts of this Complaint, in an amount that will justly compensate for the

damages, together with interest, costs and attorney fees incurred in this action, all within the jurisdictional limits of this Court.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs prays for relief against all Defendants, as follows:

a. Compensatory damages, in excess of the amount required for federal diversity jurisdiction and in an amount to fully compensate Plaintiffs for all their injuries and damages, both past and present;

b. Special damages, in excess of the amount required for federal diversity jurisdiction and in an amount to fully compensate Plaintiffs for all of their injuries and damages, both past and present, including but not limited to, past and future medical expenses, costs for past and future rehabilitation and/or home health care, lost income, permanent disability, and pain and suffering.

c. Exemplary damages

d. Punitive damages as allowed by law;

e. Attorneys' fees, expenses, and costs of this action;

f. Pre and post-judgment interest in the maximum amount allowed by law; and

g. Such further relief as this Court deems necessary, just, and proper.

JURY DEMAND

Pursuant to Federal Rule of Civil Procedure 38(b), Plaintiffs demand a trial by jury.

Dated this 29th day of September 2014.

Respectfully submitted,

PHILLIP A. KURI

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